

REMARKS

The Examiner's Office Action mailed August 13, 2008, which rejected all pending claims, has been reviewed. Reconsideration of the rejections in view of the foregoing amendments and following remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of August 13, 2008, and submit that the above Amendments and the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 1, 3, 11-19 are now in form for allowance.

Status of Claims

Claims 1, 3, 11-19 are pending in the application. Claim 2 has been canceled. Claim 1 has been amended to incorporate claim 2. Claim 3 has been amended to correct an orthographical error. No new matter has been added.

Rejection of Claims 1-3 and 11-19 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 1-3 and 11-19 under §103(a) as being unpatentable over Lange et al. (US Patent No. 5,152,986) in view of Bartel et al. (US Patent No. 6,323,213).

The claimed invention is directed to a liquid pharmaceutical preparation for oral administration. Amended Claim 1 recites a liquid pharmaceutical preparation that includes pradofloxacin bound to an ion exchange resin, characterized in that the loaded ion exchange resin is dispersed in a carrier medium comprising water and one or more pseudoplastic gel formers. The pseudoplastic gel former is selected from the group consisting of polyacrylic acid, xanthan, microcrystalline cellulose, cellulose ether, bentonite, and a mixture thereof.

The Examiner notes that Lange et al. discloses ion exchange resins which are loaded with quinolonecarboxylic acid derivatives, are dispersed in a carrier medium, and include optional excipients, such as viscosity enhancing agents. The Examiner also notes that Bartel discloses the preparation and utility of pradofloxacin, including the fact that pradofloxacin has a more potent

antibacterial action than other quinolonecarboxylic acids. Finally, the Examiner states that it would have been obvious to incorporate pradofloxacin as the quinolonecarboxylic acid in the formulation disclosed by Lange, as pradofloxacin has a more potent antibacterial action than enrofloxacin and is suitable for human and veterinary medicine. The Examiner states that it would be obvious to prepare an aqueous suspension of the formulation as this is one embodiment taught by Lange that affords an effective taste masked formulation with high uptake and high tolerance levels in animal subjects.

Applicants respectfully disagree. As the Examiner correctly notes the addition of thickeners in Lange is optional. Lange actually discloses several thickeners. The present invention requires specific pseudoplastic gel formers. These pseudoplastic gel formers ensure that the liquid composition of the present invention has stability to sedimentation. In particular, the present invention has a sort of gel-type 3-dimensional structure which helps to prevent sedimentation. Stability to sedimentation can be measured with shear viscosity and yield stress. Generally, specific pseudoplastic gel formers provide specific yield points and shear viscosity to different formulations, i.e. liquid vs. semi-solid formulations. Certain pseudoplastic gel formers would not provide adequate yield points and shear viscosity, i.e. proper stability to sedimentation, as in the present liquid invention. In addition, at column 5, lines 23-27, Lange specifically discusses that viscosity enhancing substances are added to make semi-solid preparations or oral pastes teaching away from the present invention that includes water as the carrier.

As stated in United States v. Adams, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966), combining prior art elements is not sufficient to render the claimed invention obvious if the result would not have been predictable to one of ordinary skill in the art. Although Bartel states that pradofloxacin is a quinolonecarboxylic acid and can be used in human or veterinary medicine, at this time enrofloxacin, rather than pradofloxacin, is the quinolonecarboxylic acid that is typically used and well known in the veterinary field. As such, someone

skilled in the art would not find it predictable to use pradofloxacin rather than enrofloxacin without undue experimentation.

For all the reasons stated above, Lange et al. in combination with Bartel et al. do not render claim 1 obvious. Claims 3 and 11-19 depend directly or indirectly from claim 1 and as such are also not obvious in view of Lange et al. in combination with Bartel et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are now in form for allowance.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/

Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889